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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,803	12/14/2005	Daniel T. Green	022354-000310US	7164

20350 7590 06/27/2007

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EXAMINER	
AUDET, MAURY A	
ART UNIT	**PAPER NUMBER**
1654	

MAIL DATE	DELIVERY MODE
06/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/540,803	Applicant(s) GREEN ET AL.	
	Examiner Maury Audet	Art Unit 1654	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 February 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *5,6,8-10,12-13, and 18-25*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

CHRISTOPHER R. TATE
PRIMARY EXAMINER

Continuation of 11. does NOT place the application in condition for allowance because: The reasons (rejections/art) of record and the Prior Art Made of Record But Not Relied Upon (merely recited but not deemed necessary to rely on in light of the art/rejections maintained).

Applicant's arguments are best summarized under two grounds.
Applicant's primary argument is that the prior art of record does not render obvious the present invention, following the amendment of the claims to recite the administration of "a basal replacement dose of glucagon". Applicant indicates on page 10 of the response that this "basal glucagon amount" is "about 50 to 150 picograms/ml plasma". (The claims are read in light of the specification; however, the latter is something Applicant may have given consideration to amending into the claims, to more distinctly claim the subject matter). The primary reference Houben et al. is directed to maintaining glucagon levels above those associated with a hypoglycemic state - or stated another way, administering a "basal replacement dose of glucagon" - the presently claimed invention. As provided of record, Houben et al. teaches the co-administration of insulin with glucagon, wherein glucagon IS administered in an amount via pump to maintian plasma glucagon above a "hypoglemic state". Even if not expressed in writing as such, the amount in Houben et al. equates to a "basal replacement dose of glucagon". Houben et al. is directed to administering glucagon to arrive at "about" a basal replacement dose and maintaining glucagon (while insulin is being administered) within it's mid-state, between hypoglyemic and hyperglycemic. [It is noted that any argument that Houben et al. is carried out in a non-diabetic patient is deemed wholly unpersuasive, and merely an obvious variation of a trial with a "diabetic patient" to ultimately be used in a diabetic patient - as it is clear the trials of Houben et al. are being conducted in hopes of better maintenance in a diabetic].

Applicant's second argument is that the secondary references do not remedy the "deficiences" of Houben et al. This is also not found persuasive, for the reasons of record. The only other "deficiences" in Houben et al. were simply as to the "forms" (e.g. microsome), "dosages" (e.g. ng/kg/min), and "types" (e.g. long-acting) of glucagon. Mere examples in the art were pulled as secondary references towards these every day choices made by Medical Doctors and Pharmacysts depending on standard optimizations relevant to the pharmaceutical product/patient parameters. Absent some showing of an unexpected result by Applicant by using e.g. a microsome or a dose formulated in on a scale of ng/kg/min or long-acting glucagon (OR a specific combination thereof) - that effectuates some result distinct from that expected by the same co-administration of insulin AND glucagon via pump in Houben et al. (e.g. to maintain a hypoglycemic-free state in a diabetic) - these are merely routinely optimizable parameters associated with any form of medicine, combination or otherwise. Known forms, doses, and types of known compounds or combinations do not impute an unobvious variation of the same, absent credible evidence of some unexpected result therein, either in vitro or in vivo.

For the reasons of record and further enunciated above, the Examiner maintains his position and the outstanding rejection.